Remote Interactive Monitoring of Patients on Anticoagulation Therapy to Improve Outcome and Avoid Complications

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Principle Investigator: Jennifer L. Calagan, LTC, MC
Location: Cardiology Service
Walter Reed Army Medical Center
Funding: $236,000 from MRMC

Project Description: The WRAMC Coumadin Project will evaluate both the use of patient self-testing (PST) of INR and the remote monitoring of health status in approximately 400 patients undergoing anticoagulation therapy. They will be divided into four different groups and followed for a period of one year.

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Study Groups:

Group 1: Control group, receives standard lab testing and telephone monitoring by the Coumadin® clinic

Group 2: Patients use the ProTime® PST technology and are followed with standard telephone monitoring

Group 3: Patients are monitored with the HealthBuddy® telephone device and receive standard lab testing

Group 4: Patients self-test with the ProTime® and are monitored with

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Metrics Used to Demonstrate Success/Efficacy:

The study will compare the use of both PST and remote interactive monitoring of patients to standard anticoagulation therapy management practices.

We hope to show that either or both technologies improved the efficacy and/or reduced the cost of therapy.

Part of the efficacy demonstration will involve tracking the number and severity of thrombotic or bleeding complications in each group.

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Metrics Used to Demonstrate Success/Efficacy:

The primary outcomes measured will be:

- **Quality of Care**
- **Access to Care**
- **Acceptance and Applicability of PST and Home Monitoring**
- **Cost to the Government**

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Metrics Used to Demonstrate Success/Efficacy:

Quality of Care improvements will:

- **Increase the success of the therapy and limit risk of the therapy, as measured by:**
  - **Tracking INR "time in range" (surrogate of risk/success)**
  - **Identifying and tracking complications**
  - **Enabling early discovery of impending complications and the possibility of earlier intervention**

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Metrics Used to Demonstrate Success/Efficacy:

Access to Care gains will:

- **Improve the clinic's ability to follow therapy and to**
  time and productivity "lost to therapy," as demons
  - **– Patient and clinic flow sheets documenting time**
    in managing therapy for each arm

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Metrics Used to Demonstrate Success/Efficacy:

Access to Care advances will further:

- **Improve patient access to clinic staff through He and PST technology, as shown by:**
  - **– Patient and clinic flow sheets documenting tim in managing therapy for each arm**
  - **– Patient satisfaction surveys**

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Metrics Used to Demonstrate Success/Efficacy:

Acceptance and Applicability of PST and Home Monitoring will be examined for:

- **Feasibility of using the Technology in a Military Population, as evidenced by:**
  - **Patient Surveys**
  - **Clinician Surveys**
  - **Dropout Rate**
  - **Rate of Successful Training on Devices**

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Metrics Used to Demonstrate Success/Efficacy:

Cost to Government will be measured through:

- **Time, Cost, and Productivity Lost to Monitoring T**
  - **Track time lost to duty and expense to manage medical condition or therapy and estimate cos**
  - **Cost of devices, supplies, fees, and lab services**

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Metrics Used to Demonstrate Success/Efficacy:

Cost to Government will further include:

- **Cost, Time and Productivity Lost to Complications**
  - **Tracking time lost to duty to managing comp loss of INR control**
  - **Tracking hospitalizations, ER visits and lost du time estimates (published or calculable costs)**

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Final Results:

- Protocol Revision and Approval (Jan 2000 – Apr 2001)
  - New Protocol
  - New Consent Form
  - 20 Specialized Forms
- No-Cost Service and Equipment Loan Agreement ($406,000, Dec 2000 – Mar 2001)
  - 200 HealthBuddy® devices and service
  - 200 ProTime® Devices
- Develop custom HealthBuddy® Dialogues
- Review and update over 800 patient charts

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Final Results:

- Patient Selection, Enrollment, and Training [Apr 2000 – ongoing]
- Develop Patient Database and Tracking System [20% Complete]
- Recruit, Hire and Train Clinical Staff
- Patient Care/Support
  - Training (ITC and HHN Devices) [ongoing]
  - Enrollment [ongoing]
  - Tracking [ongoing]
- Eight-Patient Pilot Test [underway]

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Problems Encountered:

- Protocol Creation and Approval Process (16 months)
- Staff Acquisition
- Lack of Electronic Patient Record or Tracking System
- Acquisition of Office Space for Staff and Patient Care
- Communications (Phone / LAN) Support
- Conduct of Manual Review of 800 Medical Records

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Potential for AMEDD-Wide Adoption:

- If proven effective, both PST and home monitoring should be suitable for AMEDD adoption
- Cost Limitation: The cost of hospitalization alone for a single systemic embolic event (including stroke) has been estimated at:
  - $11,299 if the event results in death
  - $20,887 if the patient survives
- PST and home monitoring should extend the reach of medical center expertise to remote locations

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Conclusions:

The application of the new technologies under study may improve the efficacy of therapy, at reduced risk and cost to a widespread population supported by the AMEDD.

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Questions ?